CORPORATE INTEGRITY AGREEMENT SAINT JOSEPH'S CARE GROUP

As part of the resolution of the criminal matter involving Horizon Group Enterprises, Inc. ("Horizon") and the United States Department of Justice, United States Attorney's Office for the Northern District of Indiana, this CORPORATE INTEGRITY AGREEMENT ("the Agreement") is entered into on this day of May 1998 by and between Saint Joseph's Care Group, Inc. ("Care Group") acting on behalf of its subsidiary, Saint Joseph's Medical Center that holds Medicare provider number 15-0012 and Medicaid provider number 100269940A (hereinafter referred to as "Saint Joseph's") and the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG") (collectively referred to as the "Parties").

Section 1. PREAMBLE AND RELEASE.

- 1.1. In consideration of the corporate integrity obligations undertaken pursuant to this Agreement, the HHS-OIG agrees to release and refrain from instituting, directing, or maintaining any administrative monetary claim or any action seeking exclusion from the Medicare, Medicaid or other federal health care programs against the Care Group, Saint Joseph's, and/or any affiliated entity (collectively, the Care Group, Saint Joseph's, and their affiliates are referred to as the "St. Joseph's Parties"), their current and former directors, officers, trustees and employees under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b) (permissive exclusion) for the conduct described in Section eight of the April 28, 1997 Petition to Enter a Guilty Plea (the "Petition to Enter a Guilty Plea").
- 1.2. Nothing in this Section 1 precludes the HHS-OIG from taking action against the St. Joseph's Parties or any other entity or individual for conduct or practices for which administrative claims have been reserved in Section 1.3. Further, the corporate integrity obligations in this Agreement in no way affect the compliance obligations set forth in the Petition to Enter a Guilty Plea.

- 1.3. Notwithstanding any other provision of this Agreement, the Parties to this Agreement understand that this Agreement expressly does not release the St. Joseph's Parties or their current and former directors, officers, trustees and employees or any other entity or individual from:
 - 1.3.1. any criminal, civil or administrative claims arising under Title 26 of the U.S. Code (Internal Revenue provisions);
 - 1.3.2. any liability to the United States, the State of Indiana or any agencies thereof, for any conduct other than that specifically identified in Section 8 of the April 28, 1997 Petition to Enter a Guilty Plea;
 - 1.3.3. claims against any individuals, including trustees, officers and directors of Holy Cross and Saint Joseph's, who are or may be criminally indicted or convicted, or who enter into criminal plea agreements, if such claims are based on the conduct described in Section 8 of the Petition to Enter a Guilty Plea;
 - 1.3.4. any obligations created by this Agreement;
 - 1.3.5. any claims for defective or deficient services or false claims relating to the quality of services or improper coding or double billing of services; and
 - 1.3.6. All rights and statutory obligations of the HHS-OIG to exclude parties from the Medicare or Medicaid programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion for criminal convictions non-waivable).
- 1.4. As a condition of the release and waiver of Section 1, Saint Joseph's agrees to undertake the compliance and corporate integrity obligations outlined in this Agreement for a period of five (5) years, ending April 27, 2003.

Section 2. CORPORATE INTEGRITY OBLIGATIONS.

- 2.1. Saint Joseph's agrees to implement a Corporate Integrity Program (the "Program"), as set forth below, to prevent, to the best of its ability, fraud, abuse, and false billing to the Medicare, Medicaid and other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f). The Program shall be maintained to ensure that Saint Joseph's and each of its trustees, officers, employees and contractors maintain the business integrity required of a participant in federal health care programs, and that Saint Joseph's delivery of medical care is in compliance with all laws and regulations applicable to such programs and with the terms of the Agreement set out below.
- 2.2. Saint Joseph's agrees to pursue the following course of action to ensure full and accurate compliance with Medicare, Medicaid and other federal health care program regulations and program requirements for its outpatient and inpatient hospital services provided by

Saint Joseph's its subsidiaries, its employees, and other third parties (including its independent contractors and its active staff physicians) whose services are ordered, provided, or certified as medically necessary, by Saint Joseph's personnel. Saint Joseph's shall further provide such written reports as required to HHS-OIG Office of Counsel to the Inspector General ("OCIG") detailing the actions it has taken pursuant to this Agreement.

- 2.3. Written Policies And Procedures. No later than sixty (60) days following the execution of this Agreement, Saint Joseph's shall develop and implement written compliance policies and procedures which address, at a minimum, the following:
 - 2.3.1. <u>Compliance Policies and Procedures</u>. Saint Joseph's written compliance policies and procedures shall address the proper submission of claims to Medicare, Medicaid and other federal health care programs. These policies and procedures shall conform to current statutory and regulatory guidelines and shall be updated as necessary to reflect changes in germane laws or regulations.
 - 2.3.2. <u>Corrective Actions</u>. The written policies and procedures shall also note that any known or discovered compliance deficiencies must be appropriately addressed in accordance with federal and state law and Section 4 of this Agreement.
 - 2.3.3. <u>Dissemination of Compliance Policies and Procedures</u>. Saint Joseph's written compliance policies and procedures shall require that, following their development, Saint Joseph's shall distribute these policies and procedures as soon as possible to all employees and other third parties, including its independent contractors and its active staff physicians, involved with the delivery or administration of health care services, including those involved in preparing or submitting Medicare, Medicaid and other federal health care program bills or claims at Saint Joseph's, and shall advise employees of Saint Joseph's commitment to comply with all laws and regulations and to accurately bill consistent with Medicare, Medicaid and other federal health care program regulations and procedures.
 - 2.3.4. Employee Discipline. Saint Joseph's written compliance policies and procedures shall include clear and consistently applied disciplinary policies regarding any breach of Saint Joseph's Program applicable to all employees and other third parties, including its independent contractors and its active staff physicians.
 - 2.3.5. No Contracts with Excluded Individuals. Saint Joseph's written policies and procedures shall also include a provision that Saint Joseph's shall not knowingly employ or contract with, with or without compensation, any individual, or entity currently listed by a federal agency as excluded, debarred, suspended or otherwise ineligible to participate in federal programs.

- (a) Saint Joseph's written policies and procedures shall require Saint Joseph's to make reasonable inquiry into the status of any prospective employee engaged in the delivery or billing of health care services, consultant or contractor. Such reasonable inquiry shall include, at a minimum, pre-employment review of the HHS-OIG Cumulative Sanctions Report and the General Services Administration List of Parties Excluded from Federal Procurement and Non-Procurement Programs. This GSA listing may be accessed on the Internet at http://www.arnet.gov/epls. The HHS-OIG Cumulative Sanctions Report listing is currently found on the Internet at http://www.dhhs.gov/progorg/OIG.
- 2.3.6. Payments to Physicians. Saint Joseph's shall develop, as part of its Program, written policies and procedures concerning contractual relationships with physicians. These policies and procedures shall seek to ensure that Saint Joseph's relationships with physicians conform to current statutory and regulatory guidelines and shall specifically require that, hereinafter and for the term of this Agreement, any compensation to physicians by Saint Joseph's be paid only pursuant to a written contract that has been reviewed by outside counsel. Any "form" contracts or templates relating to the compensation of physicians by Saint Joseph's must also be reviewed by counsel. Such forms or templates shall not be altered in any way without first obtaining the written advice of counsel that such modification is legally permissible.
 - (a) Access to Advice of Counsel. Evidence of review by outside counsel required by Section 2.4 shall be attached to the contracts in the files of Saint Joseph's and made available to representatives of HHS/OIG upon request. Saint Joseph's shall provide to HHS/OIG, upon request, copies of all documentation relating to Saint Joseph's policies and procedures concerning payments made to physicians, including Medical Directors and consultants, that are included in the "Administrative and General Cost Center" or other cost centers on Medicare cost reports, as well as all payments made to such physicians, in addition to their established salaries.
- 2.3.7. Prior Physician Contracts. Documents reflecting any legal review of contracts between Saint Joseph's and physicians entered into prior to the effective date of this Agreement shall be attached to the contracts in the files of Saint Joseph's within six (6) months of the date of execution of this Agreement and shall be maintained on a current basis thereafter during the term of this Agreement.

- 2.3.7. <u>Billing System</u>. Saint Joseph's shall develop written policies and procedures concerning its current billing system to ensure, to the best of its ability, that it will properly and accurately bill for services the hospital or its contractors provide to individuals covered by the Medicare, Medicaid and/or other federal health care programs.
 - (a) The policies and procedures should at a minimum require that the CPT or HCPCS code used by the billing staff to bill Medicare and Medicaid accurately describes the service that was ordered and performed and that the service was not rendered under an improper arrangement as proscribed under the Stark physician self-referral law or the Medicare and Medicaid Anti-Kickback Statute.
 - (b) Saint Joseph's shall review its current billing system and where appropriate revise or create an adequate billing system that will properly and accurately bill for services the hospital or its contractors provide to individuals covered by the Medicare, Medicaid and/or other federal health care programs.
 - (c) As part of its written policies and procedures, and within six (6) months of the execution of this Agreement, Saint Joseph's shall commit to contract with an independent professional organization, such as an accounting or law firm ("Saint Joseph's Contract"), to review on an annual basis the billing policies, procedures and practices of Saint Joseph's and its subsidiaries, consistent with Section 3 of this Agreement. The written policies and procedures and Saint Joseph's Contract will provide that the review shall be aimed at ensuring that the federal health care programs, including Indiana Medicaid are billed appropriately for services.
- 2.4. <u>Compliance Officer</u>. Saint Joseph's shall continue to employ a Compliance Officer, who shall be responsible for developing, implementing, monitoring, adapting, reporting on, and certifying compliance with policies and procedures and practices designed to ensure compliance with the requirements in this Agreement, and with the requirements of Medicare, Medicaid, and all other Federal health care programs. The Compliance Officer shall be a member of senior management of Hospital and shall make regular reports regarding compliance matters directly to the CEO and/or to the Board of Trustees of Saint Joseph's.
- 2.5. <u>Training and Education</u>. Saint Joseph's shall continue to develop and implement, on an ongoing basis, an effective training and educational program, including, at a minimum, the following elements:
 - 2.5.1. <u>Participants</u>. Saint Joseph's shall develop an effective training and educational program for Saint Joseph's personnel, including its professional and clerical employees, active staff physicians, and independent contractors ("Participants") involved in:

- (a) providing health care services, including inpatient and outpatient services;
- (b) preparing or negotiating contracts for health care services; and
- (c) preparing or submitting claims for reimbursement to the Medicare, Medicaid and other federal health care programs.
- 2.5.2. <u>Schedules and Timing</u>. Training and education pursuant to this Section 2.5 is mandatory for all Participants on the following schedule:
 - (a) Training and education must be conducted at regularly scheduled times, but at least once a year during the term of this Agreement;
 - (b) Such training shall also be included in the formal orientation of new employees, including active staff physicians and clerical employees who are, or will be, involved in those activities listing in 2.4.1. during the term of this Agreement.
- 2.5.3. <u>Content</u>. Training and education should reinforce the need for strict compliance with the law and hospital policies, and should inform employees that any failure to comply may result in disciplinary action. The training must cover, at a minimum:
 - (a) Saint Joseph's compliance program and policies as required by Section 2.3.2, above;
 - (b) Saint Joseph's voluntary disclosure program;
 - (c) Any new laws and regulations directly related to federally-funded reimbursement for health care services provided to individuals covered under Medicare, Medicaid and/or other federal health care programs, including the federal Anti-Kickback Statute, the Stark physician self-referral law, and any potential criminal, civil and administrative penalties for violations thereof;
 - (d) The submission of accurate bills for services rendered to Medicare, Medicaid and other federal care program patients; and
 - (e) The personal and ethical obligation of each individual, especially those involved in the billing process to ensure that such billings are accurate; the legal sanctions for improper billing practices; and examples of improper billing practices.

- (f) This training and education program shall be updated annually as appropriate. Training may be in the form of in-service sessions, live seminars, teleconferencing, audio or video tapes, satellite down links or such other forms as are reasonable and practical for achieving the objective established for the training or education. Documentation shall be maintained to establish that annual training has been provided, including documentation regarding the format, content, attendees, dates, and materials provided.
- 2.5.4. Saint Joseph's, in its annual report to HHS-OIG-OCIG, shall certify that such annual training has been provided, and shall include documentation regarding the format, content, attendees, dates, and materials provided in its training. Saint Joseph's shall maintain any additional documentation regarding such training on file and shall produce such documentation promptly if requested by OIG-OCIG.

Section 3. Annual Review and Monitoring.

After the first year of this Agreement, Saint Joseph's shall review the effectiveness of its Program, on an annual basis (the "Annual Review"), as follows:

- 3.1. Review of Written Policies and Procedures. Saint Joseph's shall review its written corporate policies and procedures, including its billing policies, procedures and practices attendant to the submission of claims to Medicare, Medicaid and other federal health care programs for inpatient and outpatient services. The Annual Review shall be designed to determine the accuracy and validity of inpatient and outpatient claims submitted to Medicare, Medicaid and other federal health care programs for reimbursement. The standards to be applied in the annual review are set forth below in Section 3.3.
- 3.2. <u>Billing and Contract Reviews</u>. As part of this annual review, Saint Joseph's shall also conduct an annual review of claims for reimbursement for inpatient and outpatient services designed to determine the accuracy and validity of outpatient claims submitted to federal health care programs, including the Indiana Medicaid Program. The standards to be applied in the annual review are set forth below in Section 3.3.
 - 3.2.1. As part of its Annual Review, during the term of this Agreement, Saint Joseph's shall contract with an independent professional organization, such as an accounting or law firm, to review on an annual basis the billing policies, procedures and practices of Saint Joseph's and Saint Joseph's Parties ("Saint Joseph's Contract"). The standards to be applied in the annual review are set forth below in Section 3.3.
 - 3.2.2. A summary of the identification, methodology, and results of the Annual Review, shall be retained by Saint Joseph's and included in the annual report to HHS-OIG-OCIG pursuant to Section 7 below. HHS-OIG-OCIG, may request additional supporting documentation regarding the Annual Review. Saint Joseph's agrees, subject to

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any properly asserted privilege or claim of confidentiality, to provide expeditiously any additional documentation, or reports regarding the Annual Review upon receipt of OIG's request, if such information is available.

- 3.3. <u>Standard To Be Applied In Annual Review</u>. The Annual Review shall be designed to ensure that:
 - 3.3.1. Federal health care programs are billed appropriately for services which are rendered as claimed;
 - 3.3.2. All contracts with referring persons or entities comply with all applicable state and federal laws and regulations;
 - 3.3.3. Saint Joseph's does not submit or cause to be submitted to the Medicare, Medicaid or other federal health care programs claims for patients who were referred to Saint Joseph's under contracts or arrangements that were designed to induce such referrals in violation of the Medicare and Medicaid Anti-Kickback Statute, § 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b(b), and the Stark Law, 42 U.S.C. § 1395nn; and
 - 3.3.4. Any and all payment or claims adjustments have been made in a timely fashion, per Health Care Financing Administration (HCFA) requirements.

Section 4. Ongoing Internal Review.

- 4.1. Pursuant to written policies and procedures, Saint Joseph's shall require that any known or discovered deficiencies must be appropriately addressed in accordance with federal and state law. Accordingly, if, in the ordinary course of business, or pursuant to the Annual Review, or other internal review pursuant to Saint Joseph's Program (referred to collectively hereinafter as "Ongoing Internal Review"), Saint Joseph's determines that billings submitted to federal health care programs, including the Indiana Medicaid program, violate Applicable Law, then during the term of this Agreement Saint Joseph's must address any such violation in accordance with this Section 4.
- 4.2. <u>Material Violation</u>. If any Ongoing Internal Review gives Saint Joseph's reason to suspect that there is a Material Violation of Applicable Laws at any time during the term of this Agreement (the "Discovery Date"), Saint Joseph's shall:
 - 4.2.1. Conduct reasonable inquiry or investigation,;
 - 4.2.2. Notify the HHS-OIG Office of Counsel to the Inspector General ("OIG-OGIC") in writing within sixty (60) days of the Discovery Date that a violation may have occurred and including the following information:

- (a) Saint Joseph's findings concerning the Material Violation (if any);
- (b) Saint Joseph's actions as of that date to correct such Material Violation (if any); and
- (c) Any further steps Saint Joseph's plans to take to address such Material Violation and prevent it from reoccurring in the future.
- 4.2.3. Remit to the appropriate payor, the amount of any identified overpayments, to the extent that Saint Joseph's is legally responsible for such overpayments, at the earlier of the date the overpayment is identified or sixty (60) days from the Discovery Date, along with a written description of:
 - (a) Saint Joseph's findings concerning the overpayment (if any); and
 - (b) Saint Joseph's actions as of that date to prevent future overpayments.
- 4.2.4. Implement, to the best of its ability, any necessary corrective actions to address any deficiencies within thirty (30) days of the Discovery Date (the "Initial Correction Period"). If the deficiencies cannot be reasonably corrected within the "Initial Correction Period, St. Joseph's shall submit to OCIG within the aforementioned thirty (30) days a proposed written plan detailing appropriate corrective steps Saint Joseph's. reasonably believes are required to cure, which time period shall be subject to OCIG approval. OCIG agrees not to unreasonably withhold such approval.
- 4.3. Documentation regarding the methodology and results of any investigation or inquiry conducted under this Section 4, including the implementation of corrective actions and return of overpayments, shall be retained by Saint Joseph's and included in the annual report to HHS-OIG.
- 4.4. Failure to submit a report notifying OIG-OCIG of the Material Violation will be considered a material breach of this Agreement.
- 4.5. <u>Non-Material Findings</u>. If, as a result of any Ongoing Internal Review, Saint Joseph's identifies an overpayment amount owed to a state or federal health care program, but determines that there was no Material Violation of Applicable Laws, this Agreement, or Saint Joseph's Program, Saint Joseph's agrees:
 - 4.5.1. To undertake immediate appropriate corrective actions;
 - 4.5.2. To make prompt restitution of any overpayment to the appropriate state or federal health care program within thirty (30) days from the determination that Saint Joseph's is legally responsible for any such overpayment;

- 4.5.3. To report in its Annual Report as described below in Section 6.2, the following:
 - (a) The cause of Saint Joseph's (and/or its successors' or assigns') overpayments;
 - (b) The calculation of the overpayments;
 - (c) Saint Joseph's actions to correct the cause of the overpayments; and
 - (d) Any further steps Saint Joseph's plans to take to address the cause of the overpayments and to prevent it from reoccurring in the future.

4.6. Definitions.

For purposes of this Agreement:

- 4.6.1. "Applicable Laws" are defined as those federal and state laws, regulations, and guidelines governing federal health care programs.
- 4.6.2. A "Material Violation" of Applicable Laws is one which has a significant, adverse financial impact on federal health care programs and one which affects Saint Joseph's (or its successors or assigns) continued participation in federal health care programs.

Section 5. Confidential Disclosure Program.

- 5.1. As part of its Program, and within sixty (60) days of the execution of this Agreement, Saint Joseph's shall establish a confidential disclosure program ("Hotline"), enabling employees, staff physicians, and other medical personnel and independent contractors to disclose any billings, activities, or arrangements related to the delivery of health care services or items, that may be deemed by the employee, physician or independent contractor to be inappropriate, to an identified individual or entity.
- 5.2. Saint Joseph's Hotline shall enable employees to make reports to individuals not in that employee's direct chain of command. Saint Joseph's shall post its Hotline telephone number or any other means of confidential disclosure in a prominent place accessible to each employee and shall distribute such information to each staff physician and independent contractor.
- 5.3. Saint Joseph's shall, as part of the Hotline Program, require the internal review of any reports made to the Hotline and ensure that proper follow-up is conducted.

Section 6. Certification Requirements.

- 6.1. <u>Certification</u>. Saint Joseph's agrees that it shall require annual certification by employees in management, and supervisory employees involved in the negotiation and drafting of contracts for medical services, that they have read and understand Saint Joseph's Program policies and procedures and are familiar with the procedures of the hospital's corporate compliance program. Saint Joseph's agrees to begin requiring annual certification by such employees who will certify that they:
 - 6.1.1. have received and reviewed the written policies and procedures;
 - 6.1.2. understand that compliance with the Program is a condition of their continued employment by Saint Joseph's; and
 - 6.1.3. are aware that Saint Joseph's will take disciplinary action, up to and including termination, for violation of the principles and practices set forth in the Program's written standards of conduct.
- 6.2. The annual certification may be performed during the annual training and education session required in Section 2.4, above.
- 6.3. Saint Joseph's agrees to make all annual certifications available to OIG upon request. Saint Joseph's agrees to include in the Annual Report submitted pursuant to Section 7, below, verification that all relevant employees have signed the certification statement required herein.

Section 7. Annual Reports.

- 7.1. <u>Interim Report</u>. Within 120 days after the execution of this Agreement by all parties, St. Joseph's shall report in writing to the OIG-OCIG the steps taken to develop and implement the requirements of this Agreement.
- 7.2. Annual Reports. Thirty (30) days following the date of execution of this Agreement and on or before the first, second, third, fourth, and fifth anniversaries of the signing of this Agreement, Saint Joseph's shall report in writing to the OIG-OCIG in accord with this Section 7 the status and findings of Saint Joseph's compliance efforts, including a summary of the actions taken during the preceding twelve (12) months to comply with the terms of this Agreement.

- 7.3. <u>Content</u>. The Annual Reports shall include among other things, the following:
- 7.3.1. A copy of the most recent version of the written policies and procedures as described in Section 2, above;
- 7.3.2. Copies of the schedules and training materials for the training and education programs for the previous year;
- 7.3.3. Verification by the Compliance Officer that all relevant employees have signed the certification statement described in Section 6.1, and have received the applicable compliance training and education described in Section 2.4;
- 7.3.4. A list of the number and type of all calls or communications that are related to the billing of all federal health care programs and that were made through Saint Joseph's confidential Hotline program as set forth in Section 5 and actions taken by Saint Joseph's in response to such communications;
- 7.3.5. A list of all investigations or inquiries related to the billing of all federal health care programs performed by Saint Joseph's during the preceding year as a result of Ongoing Internal Investigation or arising from obligations under Section 3 or 4 above. A summary of the identification, methodology, and results shall be provided for all inquiries undertaken;
- 7.3.6. Summaries of corrective actions taken as a result of Ongoing Internal Investigation or arising from obligations under Section 3 or 4 above, including the implementation of corrective actions and return of any overpayments; and
- 7.3.7. A summary of any and all disciplinary actions taken against employees for violations of Saint Joseph's corporate integrity policies or of state or federal laws and regulations applicable to federal health care programs.
- 7.3.8. A summary of any other material actions taken during the preceding twelve (12) months to comply with the terms of this Agreement.
- 7.4. Reporting Requirements. In all annual reports, Saint Joseph's shall provide a checklist or index of what is furnished in its annual reports and shall indicate the name or title and telephone number of the appropriate individual it has designated as the contact person for any questions or concerns that may arise relating to the reports or corporate integrity requirements under this Agreement.

7.5. All reports, requests for modification and other notification required under this Agreement shall be sent to:

Office of Counsel to the Inspector General Compliance Unit Office of Inspector General U.S. Department of Health and Human Services Cohen Building Room 5527 330 Independence Avenue S.W. Washington, D.C. 20201 (202) 619-2078 (202) 205-0604 Fax

Section 8. Inspection Rights.

In addition to any other right HHS may have by statute, regulation or contract, upon reasonable notice during the term of this Agreement, but subject to any properly asserted claims of privilege or confidentiality, HHS or any duly authorized representatives may examine all Saint Joseph's books, records and other company documents and supporting materials for the purpose of verifying and evaluating Saint Joseph's compliance with the terms of this Agreement and Applicable Law or to verify that Medicare, Medicaid or other federal health care program laws have not been violated.

Section 9. Breach and Default Provisions.

- 9.1. Saint Joseph's compliance with the terms and conditions in this Agreement shall constitute an element of Saint Joseph's present responsibility with regard to participation in federal health care programs. Full and timely compliance by Saint Joseph's shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Saint Joseph's.
- 9.2. <u>Stipulated Penalties For Failure To Comply With Certain Obligations</u>. Failure to comply with certain obligations set forth in this Agreement may lead to the imposition of the following monetary penalties (hereinafter referred to as "stipulated penalties").
 - 9.2.1. A stipulated penalty of \$1,500 for each day Saint Joseph's fails to fully and timely comply with any of the following terms:
 - (a) Creation of written policies and procedures as specified in Section 2 of this Agreement;
 - (b) Notification to OCIG of the development and institution of the education and training program, as required under Section 2 of this Agreement;

- (c) Conducting and reporting to the OIG the results of an Annual Review pursuant to Section 3 of this Agreement;
- (d) Implementation and monitoring of a confidential disclosure program as required under Section 5 of this Agreement; and
- (e) Submission of its Annual Report as required in Section 7 of this Agreement, unless prior written approval for any delay has been provided by OCIG.
- 9.2.2. A stipulated penalty of \$1,500.00 for each day Saint Joseph's employs an individual after that individual has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)). This stipulated penalty shall not be demanded if Saint Joseph's can show it has made a reasonable inquiry as to the current or potential status of the employee or consultant engaged, as described in Section 2.3.5 of this Agreement.
- 9.3. Notice of Intent to Impose Stipulated Penalties: The Demand Letter. Upon finding that Saint Joseph's has failed to comply with any of the above-enumerated obligations, OIG shall notify Saint Joseph's by certified mail of:
 - 9.3.1. Saint Joseph's alleged failure to comply; and
 - 9.3.2. OIG's exercise of its contractual right to demand payment of the stipulated penalties payable under this Agreement. (This notification is hereinafter referred to as the "Demand Letter").
- 9.4. Opportunity to Cure. Within ten (10) days of receipt of the Demand Letter, Saint Joseph's shall either:
 - 9.4.1. cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or
 - 9.4.2. request a hearing before an HHS administrative law judge to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth in Section 11 of this Agreement.
 - 9.4.3. Failure to exercise either of the above options will result in a material breach of this Agreement.
 - 9.5. Payment of Stipulated Penalties.
 - 9.5.1. The applicable stipulated penalties shall begin to accrue on the date the OIG determines the breach occurred, which date shall be indicated in the Demand Letter.

- 9.5.2. Payment of the stipulated penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OCIG at the address set forth in Section 7.4 of this Agreement.
- 9.6. These provisions for payment of stipulated penalties shall not affect, or otherwise set a standard for the OIG's determination that Saint Joseph's has materially breached this Agreement, which decision shall be made at the OIG's discretion and governed by the provisions in Section 10 of this Agreement, below.

Section 10. Remedies For Material Breach Of This Agreement.

- 10.1. If Saint Joseph's engages in conduct that OIG considers to be a material breach of this Agreement, OIG may seek exclusion of Saint Joseph's from participation in the Medicare, Medicaid and any other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)).
- 10.2. Upon making its determination, OIG shall notify Saint Joseph's of the alleged material breach by certified mail and of its intent to exclude as a result hereof (the "Intent to Exclude Letter"). Saint Joseph's shall have thirty-five (35) days from the date of the Intent to Exclude Letter to:
 - 10.2.1. cure the alleged material breach; or
 - 10.2.2. demonstrate to the OIG's satisfaction that:
 - (a) Saint Joseph's is in full compliance with this Agreement; or
 - (b) the material breach cannot be cured within the thirty-five (35) day period, but that Saint Joseph's has begun to take action to cure the material breach, that Saint Joseph's will pursue such action with due diligence, and that Saint Joseph's will give the OIG a timetable for curing the material breach.
- 10.3. If at the conclusion of the thirty-five day period (or other specific cure period as subsequently agreed to by OIG and Saint Joseph's), Saint Joseph's fails to cure the material breach to OIG's satisfaction, or otherwise fails to demonstrate either one of the requirements in Section 10.2, above, Saint Joseph's agrees to its immediate exclusion from participation in the Medicare, Medicaid and any other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). The exclusion will also apply to all other federal procurement and non-procurement programs.

- 10.4. For purposes of this Section 10, a "material breach" shall mean:
- 10.4.1. a failure to report a material billing violation, take corrective action and pay the appropriate refunds, as provided in Section 4 of this Agreement; or
- 10.4.2. repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section 2 of this Agreement.
- 10.5. In connection with the OIG's determination to exclude Saint Joseph's pursuant to this provision, Saint Joseph's shall have the right to dispute the OIG's determination in accordance with the agreed upon provisions set forth in Section 11 of this Agreement.

Section 11. Dispute Resolution.

- 11.1. Upon OIG's delivery to Saint Joseph's of its Demand Letter, or of its Intent to Exclude Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligation of this Agreement, Saint Joseph's shall be afforded review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the stipulated penalties or exclusion sought pursuant to this Agreement. Specifically, the OIG's determination to demand payment of stipulated penalties or to seek exclusion shall be subject to review by an HHS administrative law judge in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. The administrative law judge's decision, in turn, may be appealed to HHS's Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21.
- 11.2. Neither the review by an administrative law judge, nor the potential subsequent review of the administrative law judge's decision by the DAB, as provided for above, shall be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the DAB's decision shall be considered final for all purposes under this Agreement. Both parties agree to waive any rights they may have to appeal the decision administratively or judicially or otherwise.
- 11.3. All notices required under any of the aforementioned proceedings shall be given to the OIG in accordance with Section 7.4 of this Agreement.

Section 12. Appeal of Stipulated Penalties.

- 12.1. <u>Issues In A Proceeding For Stipulated Penalties</u>. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for *stipulated penalties* under Section 11 shall be:
 - 12.1.1. whether Saint Joseph's was in full and timely compliance with the obligations of this Agreement for which OIG demands payment;
 - 12.1.2. whether Saint Joseph's failed to cure; and
 - 12.1.3. the period of noncompliance.
- 12.2. <u>Burden Of Proof.</u> Saint Joseph's shall have the burden of proving that it was in full and timely compliance and the steps taken to effect the cure, if any. The OIG shall have the burden of proving Saint Joseph's failure to cure.
- 12.3. Payment of Stipulated Penalties. For purposes of paying stipulated penalties under this Agreement, and if Saint Joseph's chooses to seek review in lieu of curing the breach and paying the stipulated penalties, as set forth above, the administrative law judge's decision shall give rise to Saint Joseph's obligation to pay. Thus, payment will be due immediately after the issuance of the administrative law judge's decision. Saint Joseph's election of their contractual right to appeal to the DAB shall not excuse its obligation to make payment upon the issuance of the administrative law judge's decision.

Section 13. Appeals of Exclusion Pursuant to the Letter of Intent to Exclude.

- 13.1. <u>Issues In A Proceeding For Exclusion</u>. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issue in a proceeding for *exclusion* based on a breach of this Agreement pursuant to the Intent to Exclude Letter under Section 11 shall be:
 - 13.1.1. whether Saint Joseph's was in material breach of one or more of its obligations under this Agreement; and

- 13.1.2. whether such breach was continuing on the date of the Intent to Exclude Letter.
- 13.2. Effective Date. For purposes of the exclusion herein agreed to in the event of breach of this Agreement, the administrative law judge's decision shall be deemed to make the exclusion effective, at which time the OIG may proceed with its exclusion of Saint Joseph's, if the administrative law judge finds in favor of the OIG. The administrative law judge's decision may be appealed to the DAB in a manner consistent with the provisions in 42 C.F.R. § 1005.21.

Section 14. Notice.

14.1. Any notice to Saint Joseph's given under this Agreement shall be sent to:

Compliance Officer Saint Joseph's Medical Center 801 E. LaSalle Ave. P.O. Box 1935 South Bend, Indiana 46634-1935 219-237-7982

with copies to:

Dan Hale, Esq. General Counsel Holy Cross Health System Corporation 3606 E. Jefferson Boulevard South Bend, Indiana 46615 219-233-8558, ext. 295

Section 15. Document and Record Retention.

Saint Joseph's shall maintain for inspection documents and records relating to Medicare and Medicaid reimbursement for a minimum period of six (6) years following the execution of this Agreement, or for a longer period of time if required by state law.

Section 16. Costs Related to Compliance Plan and Settlement.

16.1. Saint Joseph's agrees that all costs, as defined in FAR 31.205-47, incurred on behalf of Saint Joseph's current or former officers or directors arising from, related to, or in connection with the Government's criminal investigations, Saint Joseph's defense and settlement thereof, the Petition to Enter a Guilty Plea, or the performance or administration of this Agreement, shall be unallowable for Medicare, Medicaid, or other Government contract accounting purposes. Saint Joseph's agrees to account separately for such costs.. Included in

these unallowable costs are any legal or related costs expended on behalf of any indicted or convicted Saint Joseph's employee.

- 16.2. Saint Joseph's also agrees to treat as unallowable the full salary and benefits costs of any officer, employee, or consultant removed from government contracting in accordance with the Saint Joseph's policy regarding employees who are indicted, debarred, suspended, or proposed for debarment, and the cost of any severance payments or early retirement incentive payments paid to employees released from the company as a result of the wrongdoing alleged.
- 16.3. In addition to the obligations assumed by Saint Joseph's under the Agreement and as described above, if HHS/OIG determines that it is necessary to conduct an independent audit or review to determine whether or to the extent to which Saint Joseph's is in material breach of its obligation under this Agreement, Saint Joseph's agrees to pay for the reasonable cost of any such audit or review. HHS/OIG agrees to notify Saint Joseph's prior to instituting any audit or review for which costs may be imposed on Saint Joseph's pursuant to this Section.

Section 17. Modification.

- 17.1. Saint Joseph's and HHS/OIG agree that any modification to this Corporate Integrity Agreement must be made by written consent of the parties to this Agreement.
- 17.2. Any and all modifications to this Agreement (including changes to dates on which an obligation is due to be met) shall be requested in writing and agreed to by OIG in writing prior to the date on which the modification is expected to take effect.

Section 18. Integration Clause.

This Agreement and the Settlement Agreement entered into by HHS/OIG and Saint Joseph's embody the entire agreement and understanding of the parties with respect to the subject matter contained herein. There are no restrictions, promises, representations, warranties, covenants, or undertakings other than those expressly set forth or referred to in this Agreement. This Agreement, together with the Settlement Agreement, supersedes any and all prior agreements and understandings between the parties with respect to such subject matter.

IN WITNESS WHEREOF, the parties hereto affix their signatures.

FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES:

Date

Lewis Morris

Assistant Inspector General

For Legal Affairs

Office of Inspector General

United States Department of Health and

Human Services

FOR SAINT JOSEPH'S MEDICAL CENTER

5/4/98

Date

Robert L. Beyer

President and Chief Executive Officer

Saint Joseph's Medical Center

801 East La Salle Ave.

South Bend, Indiana

46634

Date

Gardner, Carton & Douglas

Counsel for Saint Joseph's Medical

Center

28-Apr-98